•							PARO (SID (	00 (2 02	
							PTO/SB/ Sh	08 (2-92) eet 1 of 6	
Form PTC	)-1449			Docket Number 22627	Docket Number 226272003901		Application Number 10/615,119		
OVENEDI	_	ON DISCLO	SURE CITATION CATION	Applicant	Applicant  Carmel M. LYNCH et al.				
SEP 2 6 2003		lse several sheets if	necessary)	Filing Date July 7, 200	Filing Date July 7, 2003 Group Art Unit Note Tex Signed/6			Fied/636	
100	Ħ			Mailing Date Septemb	Mailing Date September 3 2003				
PADEMA	3.0		······································						
			U.S. PA	TENT DOCUMENTS	3				
Examiner Initials	Ref. No.	Date	Document No.	Name	Class	Subclass	Filing l Appro		
. 91	1.	12/22/1992	5,173,414	Lebkowki et al.					
87	2.	10/11/1994	5,354,678	Lebkowki et al.		X			
81	3.	12/24/1996	5,587,308	Carter et al.		X			
91	4.	08/19/1997	5,658,776	Flotte et al.					
87	5.	11/17/1998	5,837,484	Trempe et al.			_		
87	6.	02/09/1999	5,869,305	Samulski et al.					
87	7.	11/23/1999	5,990,279	Carter et al.	X				
97	8.	01/15/2002	6,338,962	Boyce					
			FOREIGN 1	PATENT DOCUMEN	NTS	· .			
Examiner Initials	Ref. No.	Date	Document No.	Country	Class	Subclass	Transl YES	lation NO	
N	9.	11/19/1995	EP 0 488 528	Europe EPO					
01	10.	05/29/1992	WO 92/08796	WIPO PCT					
91	11.	06/23/1994	WO 94/13788	WIPO PCT					
01	12.	12/08/1994	WO 94/28143	WIPO PCT					

Examiner Initials	Ref. No.	Date	Document No.	Count	ry	Class	Subclass	Trans	lation NO
91	9.	11/19/1995	EP 0 488 528	Europe EP	0				
01	10.	05/29/1992	WO 92/08796	WIPO PC					
91	11.	06/23/1994	WO 94/13788	WIPO PC	T				
01	12.	12/08/1994	WO 94/28143	WIRD PC					
01	13.	03/09/1995	WO 95/06743	WIPO PC	7				
07.	14.	05/18/1995	WO 95/13365	WIPO Pc	T				
01	15.	05/18/1995	WO 95/13392	WIPO PC	T				
81	16.	06/01/1995	WO 95/14771	WIPO PC	T				
97	17.	08/03/1995	WO 95/20671	WIPO PC	T				
27	18.	01/11/1996	WO 96/00587	WIPO PC	T				
07	19.	06/13/1996	WO 96/17947	WIPO PC	T				
91	20.	03/13/1997	WO 97/09441	WIPO pc	T				
N	21.	03/13/1997	WO 97/09442	WPO PC	7			Α.	
N	22.	09/12/1997	WO 97/32990	WERO PC	T				
EXAMI	NER:	Davis	I Jugir	DA	re consii	DERED:	8/29/0	5	

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

PTO/SB/ 08 (2-92)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

pa- 820862

Form PTQ-1449					Docket Number 226272003901		Application Number 10/615,119		
INFORMATION DISCLOSURE CITATION					Applicant				
	IN 2	AN APPLIC		Carmel M. LYNCH et al.					
SEP 2 8 2003 (Use several sheets if necessary)				Filing Date July 7, 2003		Group Art Unit	Not Yet Assi	grand /636	
•					Mailing Date September	3, 2003			,
PADEN	<b>~</b>			· · · · · · · · · · · · · · · · · · ·					
81	23.	06/25/1998	WO 98/27204	W	PO PCT				
OZ 24. 03/11/1999 WO 99/11764 WIF					PO PCT				
OTHER DOCUMENTS (including author, title, Date, Pertinent Pages, E									Pages, Etc.)
Examiner Initials	Ref. No.	Title							
87	25.	Afione, S.A. et al., (May 1996) "In vivo model of adeno-associated virus vector persistence and rescue" J. Virol. 70(5):3235-3241.							
Ø1	26.	Antoni, B.A. et al., (January 1991) "Adeno-associated virus rep protein inhibits human immunodeficiency virus type 1 production in human cells" <i>Journal of Virology</i> 65(1):396-404.							
01	27.	Arispe, N. et al., (March 1992) "Intrinsic anion channel activity of the recombinant first nucleotide binding fold domain of the cystic fibrosis transmembrane regulator protein" <i>Proc. Natl. Acad. Sci. USA</i> , Cell Biology, 89:1539-1543.							
01.	28.	Ausubel, F.M. et al., eds. (1987) <u>Current Protocols in Molecular Biology</u> , John Wiley & Sons, Inc., Table of Contents: pp. iii-xii.							
01	29.	Berns, K.I. (1990) "Chapter 62: Parvoviridae and their replication" <u>Virology</u> , Volume 2, Fields, B.N. et al. (eds.), Raven Press (New York), pp. 1743-1763.							
01	30.	Blacklow, N.R. (1988) "Chapter 11 Adeno-associated viruses of humans" Parvoviruses and Human Disease, J.R. Pattison (ed.), CRC Press, Inc., pp. 165-174.							
07	31.	Boshart, M. et al., (June 1985) "A very strong enhancer is located upstream of an immediate early gene of human cytomegalovirus" Cell 41:521-530.							
01	32.	Boulikas, T. (1996) "Common structural features of replication origins in all life forms" J. Cell. Biochem. 60:297-316.							
87	33.	Carter, B.J. (1989) "Chapter 18: Parvoviruses as vectors" <u>Handbook of Parvoviruses</u> , Volume II, Tijssen, P. (ed.) CRC Press, Boca Raton, FL, pp. 247-284.							
91	34.	Carter, B.J. (1992) "Adeno-associated virus vectors" Current Opinions in Biotechnology, 3:533-539.							
91	35.	Carter, B.J. (1989) "Chapter 11: AAV DNA replication, integration, and genetics" <u>Handbook of Parvoviruses</u> , Volume I, Tijssen, P. (ed.) CRC Press, Boca Raton, FL, pp. 169-226.							
81	36.	Chatterjee, S. et al., (1991) "Transduction of intracellular resistance to HIV production by an adeno-associated virus-based antisense vector" <u>Vaccines 91</u> , Cold Spring Harbor Laboratory Press, Chanock, R.M. et al. (eds.), pp. 85-90.							
01	37.	Chatterjee, S. et al., (November 27, 1992) "Dual-target inhibition of HIV-1 in vitro by means of an adeno-associated virus antisense vector" Science 258:1485-1488.							
Qi	38.	Chejanovsky, N. and Carter, B.J. (1989) "Mutagenesis of an AUG codon in the adeno-associate virus rep gene: Effects on viral DNA replication" Virology 173:120-128.							
EXAMI	EXAMINER: David Juga D				DATE CONSI	DATE CONSIDERED: 8/29/05			
EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.									

PTO/SB/ 08 (2-92) pa- 820862

## Form BUO-1449 RADEN INFORMATION DISCLOSURE CITATION IN AN APPLICATION

(Use several sheets if necessary)

Application Number 10/615,119 Docket Number 226272003901 Applicant Carmel M. LYNCH et al. Group Art Unit Net Yet Assigned /636 Filing Date July 7, 2003

			Mailing Date September 3, 2003				
H	39.	Clowes, M.M. et al., (February 1994) "seeded with smooth muscle cells expres 93:644-651.	Long-term biological response of injured rat carotid artery ssing retrovirally introduced human genes" J. Clin. Invest.				
01	40.	Coligan, J.E. et al., eds., (1998) in <u>Current Protocols in Immunology</u> . Volume 1, John Wiley & Sons, Inc., Table of Contents: pp. 1-9.					
81	41.		Colowick, P. (ed. in chief) et al., (1979) Methods in Enzymology, Volume LVIII, Cell Culture, Academic Press, Table of Contents: v-viii.				
69	42.	Diffley, J. (1996) "Once and only once upon a time: specifying and regulating origins of DNA replication in eukaryotic cells" Genes & Devel. 10:2819-2830.					
01	43.	Egan, M. et al., (August 13, 1992) "Defective regulation of outwardly rectifying Cl channels by protein kinase A corrected by insertion of CFTR" Nature 358:581-584.					
07	44.	Fareed, G.C. et al., (1980) "Electron microscopic methods for locating the origin and termination points for DNA replication" Methods in Enzymology, Volume 65, Grossman, L. and Moldave, K. eds., Academic Press, New York, pp. 709-717.					
H	45.	Flotte, T.R. et al., (1992) "Gene expression from adeno-associated virus vectors in airway epithelial cells" Am. J. Respir. Cell. Mol. Biol. 7:349-356.					
81	46.	Flotte, T.R. et al., (1993) "Expression of the cystic fibrosis transmembrane conductance regulator from a novel adeno-associated virus promoter" J. Biol. Chem. 268(5):3781-3790.					
61	47.	Flotte, T.R. et al., (November 1993) "Stable in vivo expression of the cystic fibrosis transmembrane conductance regulator with an adeno-associate virus vector" <i>Proc. Natl. Acad. Sci. USA.</i> Medical Sciences 93:10613-10617.					
191	48.	Flotte et al., (1995) "An improved system for packaging recombinant adeno-associated virus vectors capable of in vivo transduction" Gene Ther. 2:29-37.					
Ħ	49.	Freshney, R.I. ed. (1987) in Animal cell culture: a practical approach, IRL Press, Oxford, Table of Contents: pp. vii-xii.					
M.	50.	Gait, M.J. ed. (1984) Oligonucleotide synthesis. a practical approach, IRL Press, Oxford, Table of Contents: pp.vii-xii.					
91	51.	Giraud, C. et al., (November 1995) "Recombinant junctions formed by site-specific integration of adeno-associated virus into an episome" J. Virol. 69(11):6917-6924.					
01	52.	Giraud, C. et al., (October 1994) "Site-specific integration by adeno-associated virus is directed by a cellular DNA sequence" <i>Proc. Natl. Acad. Sci. USA</i> , Microbiology 91:10039-10043.					
01	53.	Hermonat, P.L. and Muzyczka, N. (October 1984) "Use of adeno-associated virus as a mammalian DNA cloning vector: Transduction of neomycin resistance into mammalian tissue culture cells" <i>Proc. Natl. Acad. Sci. USA</i> Genetics 81:6466-6470.					
gr	54.	Hermonat, P.L. et al., (August 1984) "Genetics of adeno-associated virus: Isolation and preliminary characterization of adeno-associated virus type 2 mutants" J. Virol. 51(2):329-339.					
EXAM	INER:	David Zun	DATE CONSIDERED: 8/29/05				

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

PTO/SB/08 (2-92) Sheet 4 of 6 Docket Number 226272003901 Application Number 10/615,119 Form PTO 5449 Applicant THE RMATION DISCLOSURE CITATION Carmel M. LYNCH et al. IN AN APPLICATION Group Art Unit Not Yet Assigned /63 6 Filing Date July 7, 2003 (Use several sheets if necessary). Mailing Date September 3, 2003 Hölscher, C. et al., (1994) "Cell lines inducibly expressing the adeno-associated virus (AAV) rep 55. gene: Requirements for productive replication of rep-negative AAV mutants" J. Virol. 68(11):7169-7177. Hölscher, C. et al., (November 1995) "High-level expression of adeno-associated virus (AAV) rep78 56. or rep68 protein is sufficient for infectious-particle formation by a rep-negative AAV mutant" J. 01 Virol. 69(11):6880-6885. Kaplitt, M.G. et al., (October 1994) "Long-term gene expression and phenotypic correction using 57. adeno-associated virus vectors in the mammalian brain" Nature Genetics 8:148-154. Kelman, Z. and O'Donnell, M. (1994) "DNA replication: Enzymology and mechanisms" Curr. Opin. 58. Genet. Dev. 4:185-195. Khleif, S.N. et al., (1991) "Inhibition of cellular transformation by the adeno-associated virus rep 59. 191 gene" Virology 181:738-741. Kornberg, A. and Baker, T.A. (1992) DNA Replication, Second Edition, Freeman, W.H. & Co., New **60**. 81 York, Table of Contents: v-ix. Kotin, R.M. et al., (December 1992) "Characterization of a preferred site on human chromosone 19q 61. 197 for integration of adeno-associated virus DNA by non-homologous recombination" The EMBO J. 11(13):5071-5078. Labow, M.A. et al., (April 1987) "Adeno-associated virus gene expression inhibits cellular **62**. PI transformation by heterologous genes" Mol. Cell. Biol. 7(4):1320-1325. Laface, D. et al. (February 1988) "Gene transfer into hematopoietic progenitor cells mediated by an 63. adeno-associated virus vector" Virology 162(2):483-486. Laughlin, C.A. et al., (November 1979) "Spliced adenovirus-associated virus RNA" Proc. Natl. 64. 07 Acad. Sci. USA Biochemistry 76(11):5567-5571. Laughlin, C.A. et al., (1983) "Cloning of infectious adeno-associated virus genomes in bacterial **65**. plasmids" Gene 23:65-73. Lebkowski, J.S. et al., (October 1988) "Adeno-associated virus: A vector system for efficient 66. 81 introduction and integration of DNA into a variety of mammalian cell types" Mol. Cell. Biol. 8(10):3988-3996. Linden, R.M. et al., (October 1996) "Site-specific integration by adeno-associated virus" Proc. Natl. 67. Acad. Sci. USA Colloquium Paper 93:11288-11294. Lupton, S.D. et al., (June 1991) "Dominant positive and negative selection using a hygromycin **68**. phosphotransferase-thymidine kinase fusion gene" Molecular and Cellular Biology 11(6):3374-3378. Lynch, C.M. et al., (April 1997) "Adeno-associated virus vectors for vascular gene delivery" Circ. **69**. Res. 80(4):497-505. McLaughlin, S.K. et al., (June 1988) "Adeno-associated virus general transduction vectors: Analysis 70. of proviral structures" J. Virol. 62(6):1963-1973. DATE CONSIDERED: **EXAMINER:** 

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

PTO/SB/08 (2-92) Sheet 5 of 6 Docket Number 226272003901 Application Number 10/615,119 Form PTQ 1449 THEORMATION DISCLOSURE CITATION **Applicant** Carmel M. LYNCH et al. IN AN APPLICATION Group Art Unit Not Yet Assigned /636 Filing Date July 7, 2003 (Use several sheets if necessary) Mailing Date September 3 2003 Mendelson, E. et al., (1988) "Expression and rescue of a nonselected marker from an integrated AAV 71. 091 vector" Virology 166:154-165. Miller, J.H. and Calos, M.P. eds., (1987) Current Communications in Molecular Biology, Gene *72.* transfer vectors for mammalian cells, Cold Spring Harbor Laboratory, Table of Contents: vii-ix. Muro-Cacho, C.A. et al., (1992) "Gene transfer in human lymphocytes using a vector based on adeno-73. 61 associated virus". J. Immunotherapy 11(4):231-237. Muzyczka, N. (1992) "Use of adeno-associated virus as a general transduction vector for mammalian 74. cells" Current Topics in Microbiol. and Immunol. 158:97-129. Rich, D.P. et al., (July 12, 1991) "Effect of deleting the R domain on CFTR-generated chloride *75*. go channels" Science 253:205.207 M Rose, J.A. (1974) "Chapter 1: Parvovirus reproduction" Comprehensive Virology 3:1-61. 76. 77. Sambrook, J. et al., (1989) Molecular cloning: a laboratory manual, 2nd edition, Cold Spring Harbor 17 Laboratory Press, Table of Contents: xi-xxxviii. Samulski, R.J. et al., (September 1989) "Helper-free stocks of recombinant adeno-associated viruses: 78. 07 Normal integration does not require viral gene expression" J. Virol. 63(9):3822-3828. Samulski, R.J. et al., (March 1982) "Cloning of adeno-associated virus into pBR322: Rescue of intact 79. 07 virus from the recombinant plasmid in human cells" Proc. Natl. Sci. USA Microbiology 79:2077-2081. Samulski, R.J. et al., (October 1987) "A recombinant plasmid from which an infectious adeno-80. 07 associated virus genome can be excised in vitro and its use to study viral replication" J. Virol. 61(10):3096-3101. Senapathy, P. and Carter, B.J. (April 10, 1984) "Molecular cloning of adeno-associated virus variant 81. genomes and generation of infectious virus by recombination in mammalian cells" J. Biol. Chem. 259(7):4661-4666. Sheppard, D.N. et al., (March 25, 1994) "The amino-terminal portion of CFTR forms a regulated Cl 82. 0/ channel" Cell 76:7091-1098. Simonsen, C.C. et al., (May 1983) "Isolation and expression of an altered mouse dihydrofolate 83. 07 reductase cDNA" Proc. Natl. Acad. Sci. USA Biochemistry 80:2495-2499. Srivastava, A. et al., (February 1983) "Nucleotide sequence and organization of the adeno-associated 84. virus 2 genome" J. Virol. 45(2):555-564. 85. Srivastiva, C.H. et al., (October 1989) "Construction of a recombinant human parvovirus B 19: Adeno-associated virus 2 (AAV) DNA inverted terminal repeats are functional in an AAV-B 19 hybrid virus" Proc. Natl. Acad. Sci. USA, Medical Sciences 86:8078-8082.

·	•	
EXAMINER:	David Juga	DATE CONSIDERED: 8/29/05

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

PTO/SB/ 08 (2-92)

Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Application Number 10/615,119 Docket Number 226272003901 Form PTQ**9**1449 CARREST OF THE CITATION **Applicant** Carmel M. LYNCH et al. IN AN APPLICATION Group Art Unit Not Yet Assigned /636 Filing Date July 7, 2003 (Use several sheets if necessary) Mailing Date September 2 2003 Tratschin, J.-D. et al., (September 1984) "Genetic analysis of adeno-associated virus: Properties of 86. deletion mutants constructed in vitro and evidence for an adeno-associated virus replication function" M J. Virol. 51(3):611-619. Tratschin, J.-D. et al., (October 1984) "A human parvovirus, adeno-associated virus, as a eucaryotic 87. vector: Transient expression and encapsidation of the procaryotic gene for chloramphenicol 91 acetyltransferase" Mol. Cell. Biol. 4(10):2072-2081. Tratschin, J.-D. et al., (November 1985) "Adeno-associated virus vector for high-frequency 88. 07 integration, expression, and rescue of genes in mammalian cells" Moll. Cell. Biol. 5(11):3251-3260. Tratschin, J.-D. et al., (August 1986) "Negative and positive regulation in trans of gene expression 89. from adeno-associated virus vectors in mammalian cells by a viral rep gene product" Mol. Cell. Biol. M 6(8):2884-2894. Urcelay, E. et al., (April 1995) "Asymetric replication in vitro from a human sequence element is 90. 0 dependent on adeno-associated virus rep protein" J. Virol. 69(4):2038-2046. Vincent, K.A. et al., (1990) "Replication and packaging of HIV envelope genes in a novel adeno-91. associated virus vector system" Vaccines 90, Cold Spring Harbor Laboratory Press, Brown, F. et al. 87 (eds.) pp. 353-359. Walsh, C.E. et al., (August 1992) "Regulated high level expression of a human y-globin gene 92. 01 introduced into erythroid cells by an adeno-associated virus vector" Proc. Natl. Acad. Sci. USA Medical Sciences 89:7257-7261. Weir, D.M. ed. et al., (1996) "Immunochemistry and molecular immunology" in Weir's Handbook of 93. Experimental Immunology, Fifth Edition, Volume 1, Table of Contents: v-xii. Weitzman, M. D. et al., (June 1994) "Adeno-associated virus (AAV) rep proteins mediate complex 94. formation between AAV DNA and its integration site in human DNA" Proc. Natl. Acad. Sci. USA

Biochemistry 91:5808-5817.

DATE CONSIDERED: **EXAMINER:** 

EXAMINER: Initial if citation considered, whether or not the citation conforms with MPEP 609. Draw a line through the citation if not in conformance and not considered. Include a copy of this form with next communication to applicant.

for the Adeno-Associated Virus Life Cycle," Journal of Virology 71(2):941-948.

Wong, K.K. et al., (1991) "Restriction of HSV-1 production in cell lines transduced with an antisense

Xiao, X. (Feb. 1997). "A Novel 165-Base-Pair Terminal Repeat Sequence Is the Sole cis Requirement

viral vector targeting the ICP4 gene" Vaccines 91, Cold Spring Harbor Laboratory Press, pp. 183-

95.

96.

189.